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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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09/881,215

06/15/2001

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50229-267

5136

7590 11/16/2007
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EXAMINER

FAY, ZOHREH A

ART UNIT

PAPER NUMBER

1618

MAIL DATE

DELIVERY MODE

11/16/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

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**BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES**

Application Number: 09/881,215
Filing Date: June 15, 2001
Appellant(s): CROOKS ET AL.

Cameron Weiffenbach
For Appellant

EXAMINER'S ANSWER

This is in response to the appeal brief filed June 20, 2007 appealing from the Office action mailed September 20, 2006.

(1) Real Party in Interest

A statement identifying by name the real party in interest is contained in the brief.

(2) Related Appeals and Interferences

The examiner is not aware of any related appeals, interferences, or judicial proceedings which will directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal.

(3) Status of Claims

The statement of the status of claims contained in the brief is correct.

(4) Status of Amendments After Final

The appellant's statement of the status of amendments after final rejection contained in the brief is correct.

(5) Summary of Claimed Subject Matter

The summary of claimed subject matter contained in the brief is correct.

(6) Grounds of Rejection to be Reviewed on Appeal

The appellant's statement of the grounds of rejection to be reviewed on appeal is correct.

(7) Claims Appendix

The copy of the appealed claims contained in the Appendix to the brief is correct.

(8) Evidence Relied Upon

Rajasekaran, "Effect of acute and repeated administration of nitric oxide (NO) precursor L-arginine, NO donor, sodium nitroprusside and NO synthase inhibitor, N (omega)-L-

Art Unit: 1618

arginine methyl ester on picrotoxin-induced seizure in rats" 6th internet world congress for biomedical science (poster 129), 2000.

Uzbay, "Effect of agmatine on ethanol withdrawal syndrome in rats" Behavioural Brain Research, 2000, Vol 107, pages 153-159.

(9) Grounds of Rejection

The following ground(s) of rejection are applicable to the appealed claims:

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 5, 7, 9, 11 and 13-20 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for treatment of seizure using agmatine, does not reasonably provide enablement for preventing seizure using agmatine. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims. The factors to be considered whether a disclosure meets the enablement requirements of 35 U.S.C. 112, first paragraph, have been described in *In re Wands*, 8 USPQ2d 1400 (Fed. Cir.1988). Among these factors are:

1) The nature of the invention:

The claims are drawn to a method of treating, ameliorating or preventing seizures using agmatine.

2) The state of the prior art:

Art Unit: 1618

The prior art does not recognize that the prevention of seizures is done easily. According to Lance, Current Medical Diagnosis and Treatment, 43rd edition, Pages 946-952, different types of seizures are treated with different agents. There are no teachings directed to prevention of seizures.

3) The relative skill of those in the art:

The relative skill of those in the art is high.

4) The predictability or unpredictability of the art:

The unpredictability of pharmaceutical and chemical art is high.

5) The breath of the claims:

The claims are very broad and encompass a composition for treating, ameliorating or preventing seizures using agmatine.

6) The amount of direction or guidance provided:

Applicant's specification provides guidance for and it is only enabled for the treatment of seizures using agmatine. Applicant's specification does not set forth a representative number of examples to demonstrate the effect of agmatine on preventing seizures.

7) The presence or absence of working examples;

The examples in applicant's specification are drawn to the effect of agmatine in treating seizures. There are no examples directed to preventing seizures using agmatine.

8) The quantity of experimentation necessary;

Art Unit: 1618

Since compound structure and activity for such pharmaceutical use must be determined from case to case by painstaking experimental study, one of ordinary skill in the art would be burdened with undue experimentation to determine the preventative effect of agmatine on seizures.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to

Art Unit: 1618

consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 5, 7, 9, 11 and 13-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Uzby et al. (2000) in view of Rajasekaran (2000).

Uzbay et al. teach the use of agmatine (40 mg) for the treatment of audiogenic seizure due to ethanol withdrawal. See page 156. Uzbay et al. further teach that the therapeutic effects are resulted from blocking nitric oxide synthesis and selective inhibition of NMDA subclass of glutamate receptor channel. The primary reference differs from the claimed invention in treating seizure caused by epilepsy. Rajasekaran et al. teach the anticonvulsant activity of agmatine used in the treatment of seizure caused by epilepsy. See pages 1-5. Rajasekaran et al. further teach the underlying mechanism for anticonvulsant activity is utilizing NO inhibition, wherein NO is produced in the neurons in response to activation by NMD receptors, see page 1. It would have been obvious to a person skilled in the art to modify Uzbay's teachings in view of Rajasekaran to treat seizure caused not only by ethanol withdrawal, but also seizure due to epilepsy.

One skilled in the art would have been motivated to combine the teaching of the above references, since one relates to the use of agmatine for the treatment of seizure caused by ethanol withdrawal, and the other relates to the anti-convulsant activity of agmatine. The above references in combination make clear that agmatine has been previously used for the treatment of seizure due to different causes. Applicant has presented no evidence to establish the unexpected or unobvious nature of the claimed

Art Unit: 1618

invention, and as such, claims 5, 7, 9, 11 and 13-20 are properly rejected under 35 U.S.C. 103 (a).

(10) Response to Argument

Appellant's arguments and remarks regarding the 112 first paragraph have been carefully considered, but are not deemed to be persuasive. Appellant refers to data in the specification to demonstrate the preventative effect of the claimed compound, agmatine. Such data do not demonstrate the prevention of seizure, which is to keep seizure from happening. Such data inhibit the occurrence of seizure in a number of animals for a limited amount of time. Such data are not representative of the prevention of seizure by agmatine. Appellant's arguments regarding the obviousness rejection have been carefully considered, but are not deemed to be persuasive. Appellant in his remarks argues that Uzbay et al. do not teach that agmatine reduces seizure at a statistical significant manner. Appellant's attention is drawn to page 156 of Uzbay reference, which teaches the effect of agmatine in "reduced both incidence and intensity of the audiogenic seizures appearing at the 6th h of ethanol withdrawal". Appellant also interprets the Uzbay et al. data as a failed attempt to treat seizure. Appellant is reminded that the prior art is silent in arriving such conclusion. Furthermore, obviousness does not require absolute predictability. The mere suggestion that agmatine is effective in reduced both incidence and intensity of seizure, creates an obviousness rejection. Appellant also argues that Rajasekaran et al. merely suggest the anti convulsant activity of arginine may be affected through agmatine. As it was discussed previously, obviousness does not require absolute predictability. The

Application/Control Number: 09/881,215
Art Unit: 1618

Page 9

Art Unit: 1618

mere fact that Rajasekaran et al. teach the anticonvulsant activity of arginine may be due to its metabolite agmatine, makes the use of agmatine as an anti-seizure drug obvious to a person skilled in the art. See In re Lambert and Konort, 192 USPQ 278 (CCPA 1976) at 280 where the court stated “; the question under 35 USC 103 is not merely what the references explicitly teach, but what they would have suggested to one skilled in the art at the time the invention was made.”.

(11) Related Proceeding(s) Appendix

No decision rendered by a court or the Board is identified by the examiner in the Related Appeals and Interferences section of this examiner's answer.

For the above reasons, it is believed that the rejections should be sustained.

Respectfully submitted,

Zohreh Fay

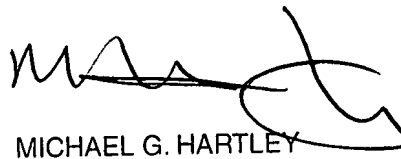
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